Obstetrical & Gynecological Associates, P.A.
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December 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

I have received a copy of your proposed rules regarding donor egg IVF. I object to the requirement to test an egg donor before the donor egg IVF cycle, freeze the resultant embryos and quarantine them until six months later when the egg donor is retested for infectious diseases and that only then are the embryos "suitable for embryo transfer."

There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.

In addition, quarantining embryos will significantly increase costs and will increase the numbers of cycles needed to obtain the same pregnancy rate. At our institution, due to differences between "fresh" versus "frozen" embryos, approximately 40% more donor cycles will be needed to get the same total number of pregnancies. Quarantining embryos will decrease the success rate for donor IVF. Also, there will be unnecessary deaths of potentially healthy embryos from the proposed rules to mandate freezing.

This delay would also cause increased stress, anxiety and possible increased health risk in the woman delaying childbirth.

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In summary, I feel that the FDA is interfering with the practice of medicine by attempting to require the quarantining of embryos resulting from donor egg IVF. There is no scientific justification (any transmission of HIV or other infectious disease) from IVF. Quarantining would increase costs, decrease success rate (pregnancy rate) and cause the unnecessary death of embryos and a delay in childbirth in many already older patients.

Please respond to my concerns and, in particular, delete the proposed rules which include donor oocytes as a part of the overall rules for the "Suitability Determination for Donors of Human Cellular and Tissue-Based Products."

Sincerely,

Leah Schenk, M.D.

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